UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP.,

Plaintiff,

v.

BLUEWILLOW BIOLOGICS, INC.; ROBIN ROE 1 through 10, gender neutral fictitious names; and ABC CORPORATION 1 through 10 (fictitious names),

Defendants.
_____ /

Case No. 21-10312

F. Kay Behm
United States District Judge

OPINION AND ORDER GRANTING BLUEWILLOW'S REQUEST TO DISMISS THIS CASE (ECF No. 92) AND DENYING PENDING MOTIONS AS MOOT (ECF Nos. 56, 57, 59, 61, 62)

In this patent infringement case, Plaintiff/Counter-Defendant Trutek Corp. ("Trutek") alleges that Defendant/Counter-Plaintiff BlueWillow Biologics ("BlueWillow") has infringed a patent owned by Trutek entitled "Electrostatically Charged Multi-Acting Nasal Application, Product, and Method," U.S. Patent No. 8,163,802 (the "'802 Patent"). (ECF No. 1, PageID.2-3). More specifically, Trutek alleges that a product named "NanoBio® Protect Nasal Antiseptic Solution" sold by BlueWillow infringes the '802 Patent. In its complaint, Trutek seeks two things

as relief: (1) damages for past sales of the NanoBio® Protect product and (2) an injunction preventing BlueWillow from manufacturing, using, selling, and importing its NanoBio® Protect product in the future.

Recently, the court granted BlueWillow's summary judgment motion of no damages, thereby denying Trutek's request for past damages. BlueWillow stated it had stopped selling its NanoBio® Protect product and that it was willing to stipulate to not sell NanoBio® Protect for the life of the '802 Patent. The court's Special Master then raised the issue of whether Trutek's request for an injunction is moot. The parties worked with the court's Special Master, and the court entered a stipulated order setting a schedule to brief the mootness issue. (ECF No. 91).

Presently before the court are BlueWillow's opening brief, Trutek's response brief, and BlueWillow's reply brief regarding mootness. (ECF Nos. 92, 93, 94). In the written briefs regarding mootness, BlueWillow requests that the court dismiss this case. (ECF No. 92). Trutek opposes BlueWillow's request, arguing that this case should proceed to adjudication of the infringement and validity issues. (ECF No. 93). Pursuant to Local Rule 7.1(f)(2), the court will decide BlueWillow's request to dismiss this case without a hearing. E.D. Mich. LR 7.1(f)(2). As explained below, the court finds that Trutek's remaining request for

injunctive relief is moot in light of BlueWillow's stipulation to not manufacture, use, sell, or import the NanoBio® Product for the life of the '802 Patent. Because the remaining issues in this case are now moot, the court **GRANTS** BlueWillow's request to dismiss this case (ECF No. 92). Accordingly, all remaining pending motions before the court are **DENIED** as moot, including: BlueWillow's motion to exclude testimony of Amirali Y. Haidri (ECF No. 56); BlueWillow's motion to exclude testimony of Alexei Ermakov and Shane Burns (ECF No. 57); the remaining portions of BlueWillow's motion for summary judgment of non-infringement, no remedy, and invalidity that have not been previously decided (ECF No. 59); Trutek's motion to exclude testimony of Mansoor M. Amiji, Ph.D. (ECF No. 61); and Trutek's motion for partial summary judgment of validity (ECF No. 62).

I. FACTUAL AND PROCEDURAL HISTORY

A. The '802 Patent and Infringement Allegations

The '802 Patent, entitled "Electrostatically Charged Multi-Acting Nasal Application, Product, and Method," was issued by the United States Patent and Trademark Office (USPTO) on April 24, 2012. (ECF No. 1, PageID.2-3). In connection with the '802 Patent, this case involves over-the-counter products that can be applied to users' nasal passages to inhibit harmful airborne particles

from causing infections through nasal inhalation. *Id.*, PageID.3. Specifically, the products include chemical formulations whose ingredients create an electrostatic charge and "catch, hold, and kill" oppositely charged particles such as allergens and viruses. *Id.*, PageID.3-4. Trutek claims that the '802 Patent covers various gels and sprays, including the technology used in Trutek's NasalGuard® product line (the "patented NasalGuard® products"). *Id.*, PageID.3. Trutek further argues that BlueWillow's NanoBio® Protect Nasal Antiseptic Solution (the "accused NanoBio® product") infringes on Claims 1, 2, 6, and 7 of the '802 Patent (the "asserted claims"). *Id.*, PageID.7.

B. Relevant Procedural History

Trutek filed this patent infringement case against BlueWillow on February 10, 2021, alleging that BlueWillow infringed the '802 Patent. (ECF No. 1). On May 19, 2021, BlueWillow filed their answer and a counterclaim for a declaratory judgment, denying that it infringed the '802 Patent and alleging that the '802 Patent is invalid. (ECF No. 9). On October 5, 2021, District Judge Stephen J. Murphy, III[1] granted in part and denied in part Trutek's motion to dismiss BlueWillow's counterclaims for declaratory judgment. (ECF No. 15). Specifically,

[1] This case was initially before District Judge Stephen J. Murphy, III, but was reassigned to the undersigned on February 6, 2023.

Judge Murphy's order dismissed BlueWillow's non-infringement counterclaim but retained BlueWillow's invalidity counterclaim. *Id.* On June 2, 2022, Judge Murphy denied Trutek's first motion for leave to amend the complaint to add an infringement claim as to BlueWillow's developmental vaccine candidates. (ECF No. 32). On November 17, 2022, Judge Murphy also denied Trutek's second motion for leave to amend the complaint to add a willful infringement claim as to BlueWillow's post-suit sales of the accused NanoBio® product. (ECF No. 50).

On September 19, 2023, the court issued an opinion and order deciding the damages issues in this case (the "Damages Order"). (ECF No. 84). In the Damages Order, the court held that Trutek cannot recover damages in this case on two independent grounds: (1) under Federal Rule of Civil Procedure 56 because "Trutek cannot meet its burden of proving the amount of damages," and (2) as a discovery sanction under Federal Rule of Civil Procedure 37(c)(1) because "Trutek never adequately asserted a claim for damages." *Id.*, PageID.4258, 4275. On January 17, 2024, the court denied Trutek's motion for reconsideration of the portion of the Damages Order granting BlueWillow's motion for summary judgment of no pre-suit damages. (ECF No. 95).

C. Additional Events

BlueWillow removed the accused NanoBio® product from the market shortly after this case was filed. (ECF No. 76, PageID.3179 ("Defendant continued to sell its NanoBio® Protect product for approximately two-to-three additional months"); ECF No. 92, PageID.4430 ("NanoBio® Protect is no longer sold and has not been sold since shortly after this case was filed")). Additionally, Trutek does not dispute that BlueWillow has no plans to reintroduce the accused NanoBio® product to the market. Moreover, BlueWillow explains that "BlueWillow has further offered to execute a stipulation agreeing not to make, use, sell, offer to sell, or import NanoBio® Protect at any time in the future." (ECF No. 92, PageID.4430). In an effort to confirm this fact, BlueWillow submits a declaration from BlueWillow's President and CEO Chad Costley, MD, MBA. (ECF No. 94-1). Dr. Costley states that: "BlueWillow will not sell NanoBio® Protect at any time in the future and is willing to execute and file a stipulation with the Court confirming this fact." *Id.*, PageID.4478.

Trutek acknowledges that the offered stipulation "does purport to protect against future sale of the infringing product," but demands coverage of "not just the NanoBio® Protect product but the infringing technology at the core of both NanoBio® Protect and the developmental vaccines." (ECF No. 93, PageID.4450-

51). "While Trutek acknowledges that it cannot currently proceed with claims based on the developmental vaccines," Trutek argues that "the cationic surfactant adjuvant technology used to deliver those vaccines is nonetheless relevant to the present litigation as it is the same cationic technology at issue with the nasal product." *Id.*, PageID.4448. According to Trutek, "the availability of relief rests upon the use of that infringing technology in BlueWillow products," and "the fact that Trutek cannot bring a current claim for infringement based on the cationic surfactant adjuvant technology of the vaccines does not disappear evidence of the infringing technology underlying them." *Id*.

II. RELEVANT LEGAL STANDARDS

Article III of the Constitution limits the jurisdiction of federal courts to "Cases" or "Controversies." U.S. Const. art. III, § 2. The doctrine of constitutional standing serves to identify which disputes satisfy Article III's case-or-controversy requirement and therefore may be resolved by a federal court. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992). In the context of a patent infringement case, standing is derived from the Patent Act and its creation of a legally protected interest in the right to exclude others from practicing the patented invention. *WiAV Sols. LLC v. Motorola, Inc.*, 631 F.3d 1257, 1264-65 (Fed. Cir. 2010).

The Supreme Court has held that standing includes three elements: the plaintiff (1) suffered an injury in fact, (2) that was caused by the defendant's conduct, and (3) will likely be redressed by a favorable decision. *Lujan*, 504 U.S. at 560-61. An injury in fact is "an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical." *Id.* at 560 (quotations and citation omitted). The plaintiff has the burden of establishing injury in fact, causation, and redressability. *Id.* at 561. The plaintiff must demonstrate standing separately for each claim it asserts and each form of relief it seeks. *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006). "Since they are not mere pleading requirements but rather an indispensable part of the plaintiff's case, each element must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, i.e., with the manner and degree of evidence required at the successive stages of the litigation." *Lujan*, 504 U.S. at 561.

The Supreme Court has held that an actual controversy must exist through all stages of litigation. *Already, LLC v. Nike, Inc.*, 568 U.S. 85, 90-91 (2013). "A case becomes moot—and therefore no longer a 'Case' or 'Controversy' for purposes of Article III—when the issues presented are no longer 'live' or the parties lack a legally cognizable interest in the outcome." *Id.* at 91. However, "a

defendant cannot automatically moot a case simply by ending its unlawful conduct once sued." *Id.* Under the voluntary cessation doctrine, "a defendant claiming that its voluntary compliance moots a case bears the formidable burden of showing that it is absolutely clear the allegedly wrongful behavior could not reasonably be expected to recur." *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 190 (2000).

III. ANALYSIS

As BlueWillow points out, Trutek asserts a single claim of infringement as to the accused NanoBio® product, and seeks two forms of relief for infringement, damages and an injunction. (ECF No. 1). Given the events of this case, BlueWillow argues that it should be dismissed for lack of standing. Specifically, BlueWillow argues that Trutek no longer has standing to maintain this case because Trutek's only requests for relief are moot. BlueWillow's basic premise is that any relief must be limited to infringement by the accused NanoBio® product. As to past infringement, BlueWillow argues that Trutek's request for damages is moot because the court has held that Trutek cannot recover damages. As to future infringement, BlueWillow argues that Trutek's request for an injunction is moot because BlueWillow has offered to stipulate to not selling the accused NanoBio® product in the future.

Trutek argues that this case should proceed to adjudication of the infringement and validity issues. Trutek generally does not rebut BlueWillow's arguments except to challenge their basic premise that any relief must be limited to the accused NanoBio® product. "The crux of the case before the court," Trutek argues, "is BlueWillow's use of Trutek's patented 'electrostatically charged nasal application' technology," and "BlueWillow has used this technology in both NanoBio® Protect and its developmental vaccines." (ECF No. 93, PageID.4449). According to Trutek, "the availability of relief rests upon the use of that infringing technology in BlueWillow products," and "the fact that Trutek cannot bring a current claim for infringement based on the cationic surfactant adjuvant technology of the vaccines does not disappear evidence of the infringing technology underlying them." *Id.*, PageID.4448. Trutek argues that injunctive relief is a "live" issue because "BlueWillow's offer is not sufficiently comprehensive enough to negate the possibility that direct or similar infringement would not recur," and therefore "injunctive relief remains a viable remedy that would redress Trutek's injury threatened by future infringement." *Id.*, PageID.4453.

In addition to the above issue of injunctive relief, the parties raise the previously resolved issue of damages, as well as the newly presented issue of

declaratory relief. Below, the court will address the damages, injunctive relief, and declaratory relief issues raised by the parties in turn. For the reasons set forth below, the court declines to revisit the issue of damages. Additionally, the court finds that Trutek's request for an injunction is moot. Lasty, the court finds that declaratory relief would be unnecessary and inappropriate in this case.

A. Damages

In a section on purportedly "Unresolved Matters," Trutek urges the court to revisit the issue of damages. Specifically, Trutek argues that the "sales document" discussed in the Order "includes data on sales commissions and fees" and therefore "yields enough data to determine a reasonably royalty and thus a damages calculation." (ECF No. 93, PageID.4457-4459). The court declines to consider Trutek's argument for a commissions-based reasonable royalty theory. In the court's previous summary judgment Order, the court fully resolved and did not order further briefing on the issue of damages. In addition to being unauthorized, Trutek's argument has long been waived. Trutek did not present a commissions-based reasonable royalty theory in either of its oppositions to BlueWillow's motions (ECF Nos. 43, 76) or in its own motion for reconsideration (ECF No. 89). Moreover, Trutek's argument is factually unsupported. The court could not pass on the merits of Trutek's argument because Trutek has not placed

the sales document in the record. *See* Fed. R. Civ. P. 56(c)(1)(A) (requiring a party to support factual assertions by "citing to particular parts of materials in the record"). Notably, the court has admonished Trutek for the same failure on two previous occasions. (ECF No. 50, PageID.1045 (noting that Trutek "did not attach the financial records to its motion" and therefore "failed to support its argument with any facts about the financial records"); ECF No. 84, PageID.4266, 4270 (noting that "the sales document is not of record" and that "Trutek's arguments are generally unsupported" in part because of its limited "descri[ption of] the information in the sales document")).

B. Injunctive Relief

The parties dispute whether BlueWillow mooted Trutek's request for an injunction under the voluntary cessation doctrine. As noted above, BlueWillow removed the accused NanoBio® product from the market shortly after this case was filed. Moreover, BlueWillow has no plans to reintroduce the accused NanoBio® product to the market, and has offered to stipulate to not selling the accused NanoBio® product in the future. In addition to BlueWillow's representations on the record (*e.g.*, ECF No. 92, PageID.4430), BlueWillow's President and CEO states in a declaration that: "BlueWillow will not sell NanoBio®

Protect at any time in the future and is willing to execute and file a stipulation with the Court confirming this fact." (ECF No. 94-1, PageID.4478).

Both parties treat the offered stipulation in this case as analogous to the "covenant" from the Supreme Court's *Already* decision. *Already*, 568 U.S. at 89. Given BlueWillow's argument that Trutek's request for an injunction is moot, the court interprets the offered stipulation as a covenant that BlueWillow will not make, use, sell, offer to sell, or import the accused NanoBio® product until after the '802 Patent expires. Accordingly, the covenant is coextensive with Trutek's infringement claim, alleging infringement by the accused NanoBio® product, and Trutek's requested injunctive relief, an injunction prohibiting sales of the accused NanoBio® product. (ECF No. 1). Under the voluntary cessation doctrine, the court finds that BlueWillow has met its burden of showing that "the allegedly wrongful behavior," infringement by the accused NanoBio® product, "could not reasonably be expected to recur." *Friends of the Earth*, 528 U.S. at 190. Accordingly, the court finds that Trutek's request for an injunction is moot.[2]

[2] The court notes that BlueWillow also moved for summary judgment of no injunctive relief. (ECF No. 59). BlueWillow presented a reasoned argument, applying the applicable legal standard to the facts of this case, that Trutek is not entitled to injunctive relief. *Id.*, PageID.1695-96 (citing *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006)). Among other things, BlueWillow argued "there is no ongoing irreparable injury to Trutek" because "BlueWillow's products in development are all intranasal vaccine products, a business that Trutek is not engaged in." *Id.*, PageID.1695. As noted in the Damages Order, Trutek did not respond to BlueWillow's argument. (ECF No. 84, PageID.4281).

Despite the covenant giving Trutek exactly what it requested in the complaint, Trutek is not satisfied with the covenant because it does not cover the developmental vaccines. For background, BlueWillow's developmental vaccine candidates are not, and cannot be, part of this case because they "are protected under the safe harbor provision of 35 U.S.C. § 271(e)(1)." (ECF No. 32, PageID.515). In the Patent Act, the safe harbor of Section 271(e)(1) is an "exemption" to the "general rule" that the acts described in Section 271(a) constitute infringement. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 195 (2005) (citing 35 U.S.C. §§ 271(a), 271(e)(1)). When Trutek moved for leave to amend the complaint to add an infringement claim as to BlueWillow's developmental vaccine candidates, the court denied Trutek's motion as futile. (ECF No. 32, PageID.515-17).

Trutek "acknowledges that it cannot currently proceed with claims based on the developmental vaccines," but argues that "injunctive relief remains a viable remedy that would redress Trutek's injury threatened by future infringement." (ECF No. 93, PageID.4448, 4453). However, Trutek does not cite any authority for the proposition that a defendant's voluntary cessation must remove different injuries that the plaintiff alleges for unpled claims, let alone futile unpled claims. Moreover, Trutek's reliance on future infringement to avoid

mootness assumes that Trutek has established injury in fact. "Although the voluntary cessation standard requires the defendant to show that the challenged behavior cannot reasonably be expected to recur," the Supreme Court has explained that the doctrine does not "allow[] the plaintiff to rely on theories of Article III injury that would fail to establish standing in the first place." *Already*, 568 U.S. at 96.

To establish injury in fact, Trutek must show that infringement by the developmental vaccines is "actual or imminent," as distinguished from "conjectural or hypothetical." *Lujan*, 504 U.S. at 560 (quotations omitted). Without factual support, Trutek maintains that injury is "sufficiently immediate" because BlueWillow is "far along" in the developmental process, and the developmental vaccines are "due to be brought to market." (ECF No. 93, PageID.4453, 4456). This is not enough to establish injury in fact. On summary judgment, Trutek cannot rely on such "mere allegations," but instead "must set forth by affidavit or other evidence specific facts." *Lujan*, 504 U.S. at 561 (quotations omitted). In any event, BlueWillow has shown that Trutek's allegations are untrue. As stated by BlueWillow's President and CEO: "BlueWillow's vaccine candidates are in the early stages of the overall development process, ether in pre-clinical or clinical Phase I testing." (ECF No. 94-

1, PageID.4480). "Based on the current development status, BlueWillow does not expect any of its developmental vaccine candidates to receive FDA approval and be commercialized in the U.S. for more than five years." *Id.*, PageID.4480-81.

The court also notes that Trutek's strained reliance on the developmental vaccines illustrates that its demands for the covenant to cover the developmental vaccines are unreasonable. Specifically, the court could not presently grant injunctive relief directed to the developmental vaccines for two reasons. First, the parties have not litigated the issue of infringement by the developmental vaccines. The Federal Circuit has held that injunctive relief must be predicated on a judgment of infringement, and that the scope of judgment cannot extend beyond the issues that were actually litigated and adjudicated. *Eli Lilly & Co. v. Medtronic, Inc.*, 915 F.2d 670, 674 (Fed. Cir. 1990) (vacating district court's injunction for lacking the "necessary predicate" of "a judgment of infringement"); *Microsoft Corp. v. DataTern, Inc.*, 755 F.3d 899, 911 (Fed. Cir. 2014) (reversing district court's grant of declaratory judgment of infringement as to products other than the "only" accused product that "was fairly at issue").

Here, Trutek does not dispute that the parties never conducted discovery on the developmental vaccines. Likewise, the record on summary judgment shows that Trutek's "infringing" label amounts to an unproven allegation. In the

joint discovery plan, Trutek explained that the developmental vaccines "were not tested to determine infringement of the patent claims with certainty," and that "due to a lack of precise knowledge of the ingredients and composition," Trutek's technical expert was only able to reach the conclusion that they "probably infringe." (ECF No. 18, PageID.235). "Regardless of theoretical considerations," Trutek's technical expert explained, "without such an analysis, infringement of the claims of the '802 patent by the BlueWillow vaccines cannot be definitely established." (ECF No. 30-6, PageID.493).

Second, as noted above, the court has found that the developmental vaccines are protected under the safe harbor. Contrary to Trutek's "infringing" label, BlueWillow's vaccine activities do not presently constitute infringement. Likewise, in an effort to avoid mootness as to injunctive relief, Trutek incorrectly relies on the standards for seeking declaratory relief. (ECF No. 93, PageID.4447-48 (Trutek arguing that "[e]vidence of meaningful preparation to make, sell, or use an object subject to an infringement charge can be used to show the potential for future infringement, so long as that future infringement is real and imminent") (quotations omitted)). As distinguished from declaratory relief, the Federal Circuit has held that injunctive relief must be predicated on actual acts of infringement. *Lang v. Pac. Marine & Supply Co.*, 895 F.2d 761, 765 (Fed. Cir. 1990)

(affirming district court's dismissal of patentee's request for an injunction against threatened infringement for failure to state a claim). Moreover, even when prohibiting other acts of infringement, the Patent Act expressly forbids courts from granting injunctive relief that would prohibit the accused infringer from practicing the patented invention under the safe harbor. 35 U.S.C. § 271(e)(3). In light of the statutory language, the Federal Circuit has held that courts cannot issue an injunction "until the § 271(e)(1) exception has been adjudicated and ruled out." *Eli Lilly*, 915 F.2d at 674 (vacating district court's injunction for covering "all of" the accused infringer's activities "without a determination that any activities fell outside the purview of section 271(e)(1)"). Accordingly, even if Trutek was entitled to injunctive relief directed to the accused NanoBio® product, an injunction would have to specifically exclude BlueWillow's vaccine activities.

C. Declaratory Relief

Lastly, the parties raise the issue of declaratory relief. Trutek did not plead a claim for a declaratory judgment, but maintains that declaratory relief "remains open to Trutek." (ECF No. 93, PageID.4453). In a section on "Trutek's Request for Declaratory Relief," Trutek directs the court to its motion for partial summary judgment of validity (ECF No. 62), where "Trutek requests a declaratory judgment with respect to patent validity and infringement." *Id.*, PageID.4454. Conversely,

BlueWillow asserts a counterclaim for declaratory judgment of invalidity, but does not address its invalidity counterclaim. The court presumes that BlueWillow's request to dismiss this case entails consent to dismiss BlueWillow's invalidity counterclaim along with Trutek's infringement claim.

As best understood by the court, Trutek argues that this case should proceed in the normal course to adjudication of the infringement and validity issues, with final judgment serving as declaratory relief. As to liability for patent infringement, the only issues that the parties have litigated are: (1) infringement by the accused NanoBio® product; and (2) the validity of the '802 Patent. (ECF Nos. 59, 62). The Declaratory Judgment Act provides that "[i]n a case of actual controversy within its jurisdiction, … any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration." 28 U.S.C. § 2201(a). The party seeking to base jurisdiction on the Declaratory Judgment Act has the burden of proving that "the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007). "Since its inception, the Declaratory Judgment Act has been understood to confer on

federal courts unique and substantial discretion in deciding whether to declare the rights of litigants." *Wilton v. Seven Falls Co.*, 515 U.S. 277, 286 (1995).

In the patent context, the Federal Circuit has explained that declaratory judgment actions are generally brought by potential future infringers against patentees, or by patentees against threatened future infringers. *Lang*, 895 F.2d at 763-64. For instance, "the purpose of the Declaratory Judgment Act" for potential future infringers "is to provide the allegedly infringing party relief from uncertainty and delay regarding its legal rights." *Goodyear Tire & Rubber Co. v. Releasomers, Inc.*, 824 F.2d 953, 956 (Fed. Cir. 1987). "The real value of the judicial pronouncement—what makes it a proper judicial resolution of a 'case or controversy' rather than an advisory opinion—is in the settling of some dispute *which affects the behavior of the defendant towards the plaintiff*." *Hewitt v. Helms*, 482 U.S. 755, 761 (1987).

The court finds that declaratory relief as to the infringement and validity issues would be unnecessary and inappropriate in this case. Initially, to the extent Trutek "moves for summary judgment of validity of U.S. Patent 8,163,802" (ECF No. 62, PageID.2607), the court cannot grant declaratory judgment of validity. The Federal Circuit has explained that "a declaratory judgment of patent validity … is not a viable cause of action." *Semiconductor Energy Lab. Co., Ltd. v. Nagata*,

706 F.3d 1365, 1370 (Fed. Cir. 2013); *see also Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1569 (Fed. Cir. 1987) (explaining that a court does not "declare a patent valid" but rather states "only whether the patent challenger carried its burden of establishing invalidity in the particular case before the court").

Moreover, as to the infringement issue, the court cannot grant declaratory relief that affects BlueWillow's behavior toward Trutek. The court has held that Trutek cannot recover damages, and BlueWillow already removed the accused NanoBio® product from the market. Accordingly, a favorable judgment to Trutek would amount to nothing more than a declaratory judgment of past infringement. Rather than properly affecting BlueWillow's behavior, Trutek's above arguments make clear that its only interest in a favorable judgment is to further its unsubstantiated and premature demands against the unlitigated and safe harbor-protected developmental vaccines. Indeed, Trutek does not rebut BlueWillow's argument that Trutek "seeks declaratory relief for improper reasons, namely for use in speculative, as-yet unfiled lawsuits related to activity the court has already found exempt from infringement under the safe harbor of 35 U.S.C. § 271(e)(1)." (ECF No. 92, PageID.4423).

D. Summary

As set forth above, the court has previously held that Trutek cannot recover damages, and presently finds that Trutek's request for an injunction is moot.[3] As well, the court finds that declaratory relief as to the infringement and validity issues would be unnecessary and inappropriate in this case. Having disposed of Trutek's requests for relief and declined to adjudicate Trutek's infringement claim, the court concludes that dismissal of this case with prejudice is appropriate. Accordingly, the court will **GRANT** BlueWillow's request to dismiss this case. (ECF No. 92). Finally, the court will **DENY** all the remaining pending motions as moot, including: BlueWillow's motion to exclude testimony of Amirali Y. Haidri (ECF No. 56); BlueWillow's motion to exclude testimony of Alexei Ermakov and Shane Burns (ECF No. 57); the remaining portions of BlueWillow's motion for summary judgment of non-infringement, no remedy, and invalidity

[3] While the outcome of dismissal is warranted because the remaining issues in this case are moot, the court does not find that this case, as a whole as filed, was moot, such that dismissal for lack of standing is appropriate. Specifically, the court is not persuaded by BlueWillow's mootness argument as to damages. As discussed above, BlueWillow has presented a persuasive argument that BlueWillow mooted Trutek's request for an injunction under the voluntary cessation doctrine. However, BlueWillow does not cite any doctrine under which the court mooted Trutek's request for damages. As explained by the district court in a decision cited by BlueWillow, although "[i]t might seem that the case has become moot, because the parties cannot obtain any benefit from further proceedings," "that is not correct," "because a failure of proof, whether with respect to liability or to remedy, while it ends a case does not make the case moot." *Apple, Inc. v. Motorola, Inc.*, 869 F. Supp. 2d 901, 924 (N.D. Ill. 2012) (Posner, J., sitting by designation).

that have not been previously decided (ECF No. 59); Trutek's motion to exclude testimony of Mansoor M. Amiji, Ph.D. (ECF No. 61); and Trutek's motion for partial summary judgment of validity (ECF No. 62).

IV. CONCLUSION

For the reasons stated in this opinion and order, the court hereby **ORDERS** that this case is dismissed as follows: Trutek's complaint (ECF No. 1) is **DISMISSED WITH PREJUDICE**; and BlueWillow's counterclaim (ECF No. 9) is **DISMISSED WITHOUT PREJUDICE**

SO ORDERED.

Date: February 2, 2024

s/ F. Kay Behm
F. Kay Behm
United States District Judge